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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,966	10/02/2001	John A. Stolk	210121.484C6	3194

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EXAMINER	
ZEMAN, MARY K	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/05/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/970,966	Applicant(s) STOLK ET AL.	
	Examiner Mary K Zeman	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 22-24 are pending in this application. Claims 14 and 19-21 have been canceled.

Applicant's arguments filed 2/10/03 have been fully considered but they are not persuasive.

Rejections Maintained

Claims 22-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection. To the extent this rejection is newly applied it is necessitated by Applicant's amendments.

Applicant argues that the description of SEQ ID NO: 199 and 214 and how they were cloned provides adequate written description for the enormous genus of polynucleotides falling within the scope of claims 22-24. This is not persuasive. Applicant provides no specific arguments rebutting the Examiner's position, and appears to indicate that probes of merely 10 base pairs are specific, even in the face of the documented unrelated sequences set forth previously. The new claims do not overcome the issues set forth previously and these arguments are reiterated herein.

The specification sets forth SEQ ID NO: 199, and SEQ ID NO: 210, 211 and 214 and how they was cloned.

The claims are drawn to methods of detecting ovarian cancer using oligonucleotides of at least 10 base pairs that hybridize to SEQ ID NO: 199, or 214, and to methods of detecting ovarian cancer using primers of at least 10 base pairs of SEQ ID NO: 199 or 214. The specification does not provide written description of the genus of oligonucleotides encompassed by the claims. The sequences range from a few hundred bases in length to a few thousand. The minimal length set for the oligonucleotide probes does not render a 10 bp fragment specific to ovarian cancer, nor is there an indication of which ten bases to utilize. There are no limits on hybridization conditions, and no limits on the sequence identity required in order to be specific for SEQ ID NO: 199 (or any other sequence) such that their use would enable the detection of ovarian cancer. There is no indication of how one is to identify portions of SEQ ID NO: 199 or things that hybridize to it which would allow one to detect ovarian cancer. The genus of

oligonucleotides required to practice the invention are only described by their ability to hybridize to the elected sequence, or amplify an encoded sequence.

By way of example, the examiner has provided various sequences that have stretches of complete identity to one or more of the sequences identified above. There is enormous variety in the types of sequences shown to have some stretches of complete, or high levels of identity. (complete identity would, by definition, hybridize) Probes from these sequences and primers from these sequences would appear to meet the limitations of the claim- but would not appear to be diagnostic for ovarian cancer. Sequences from human and mouse are present, and the sequences were derived from a wide variety of sources including:

melanotic melanoma (Genbank BE385990 21 July 2000- having about 400 contiguous bases of SEQ ID NO: 214); This is a significantly different cancer than ovarian cancer. Applicant has provided no arguments or evidence that any partial sequence (other than full length) can distinguish them.

anaplastic oligodendroma (Genbank AI936826 08 March 2000- the complement of which has about 200 contiguous bases to SEQ: 210 and 211); This is a significantly different cancer than ovarian cancer. Applicant has provided no arguments or evidence that any partial sequence (other than full length) can distinguish them.

medulloblastoma (Genbank AW149665 03 November 1999- having about 150 contiguous nucleotides of SEQ: 210 and 211); This is a significantly different cancer than ovarian cancer. Applicant has provided no arguments or evidence that any partial sequence (other than full length) can distinguish them.

well-differentiated endometrial adenocarcinoma (Genbank AW150789 03 November 1999- the complement of which has about 200 contiguous nucleotides of SEQ ID NO: 210); This is a significantly different cancer than ovarian cancer. Applicant has provided no arguments or evidence that any partial sequence (other than full length) can distinguish them.

Finally, infant brain (Genbank H06756 21 June 1995 having about 200 contiguous nucleotides of SEQ:199).

Are each of these partial sequences identical to portions of the elected sequences diagnostic for human ovarian cancer? These sequences are not described in the specification, nor are there indications of what probes to use, other than the full length sequence, that would be

diagnostic for ovarian cancer. The claims as written do not require hybridization across the entire length of the sequence, nor do they require amplification of the entire sequence.

The courts have previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has only been defined by a statement of function or result and have held that such a statement did not adequately describe the claimed invention. Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406. In Eli Lilly, the court concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. Id. at 1567, 43 USPQ2d at 1405. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. Id. The court stated that an adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. at 1568, 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

While the description of the ability of the claimed probe to bind to SEQ ID NO: 199 may describe the probe's function, it does not describe the probe itself. The hybridization distinguishes the claimed nucleotide sequences from unclaimed sequences only by what they do, which is a purely functional distinction.

The specification does not set forth any particular probes, other than the full length sequence, that hybridize to SEQ ID NO: 199, 210, 211 or 214 and are diagnostic for ovarian cancer such that one could consider a representative number of species of the genus as being described. The specification merely sets forth a multitude of vague recitations as to what oligonucleotide probes could be, what lengths they could have, and what conditions might be useful. None of these satisfy the written description requirement.

The examiner has considered the disclosure in light of the Written Description Guidelines. The hybridization set out in the present claims is the only characteristic purportedly describing the claimed nucleotide sequences. The Guidelines do not provide that a nucleotide

sequence may be defined only by its function. Describing a complicated molecule by means of a broad generic term (a nucleotide sequence) plus its function fails to distinguish it from other molecules that can perform the same function. Thus, in the absence of sequence information for its hybridization site, a nucleic acid described only by its ability to hybridize with another DNA fails to meet the requirements of § 112, ¶ 1.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (703) 305-7133.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at (703) 308-4028.

Official fax numbers for this Art Unit are: (703) 308-4242, (703) 872-9306. An *unofficial* fax number, direct to the Examiner is (703) 746 5279. Please call prior to use of this number.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC1600 Receptionist whose telephone number is (703) 308-0196.

mkz
5/2/03

MARY K. ZEMAN
PRIMARY EXAMINER
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